ISRCTN17962845 https://doi.org/10.1186/ISRCTN17962845

Analysing data from patient medical records to investigate whether a 18FDG-PET scan can predict survival in patients with breast cancer that can be treated with surgery

Submission date
09/05/2020

Recruitment status
No longer recruiting

Registration date
12/05/2020

Overall study status
Completed

Last Edited
14/06/2023

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Background and study aims
Most cancers use more glucose (a type of sugar) than normal cells. FDG is a molecule that is taken up by cancer cells in the same way as glucose and can be visualised in a PET scan to show where there are tumours in the body. This technique is widely used to investigate whether breast cancer has spread to other areas of the body, but it is not clear whether it would also be useful in the early stages of breast cancer, when the cancer can still be treated with surgery alone.
This study will use medical records of patients diagnosed with breast cancer at a Brussels hospital in the years from 2002 to 2015. It will look at the FDG-PET imaging the patients received and how long they survived without cancer and in total to see if there are any patterns.

Who can participate?
There is no active participation in this study. Medical records of people treated 2002-2015 will be analysed.

What does the study involve?
The researchers will take information from medical records and FDG-PET scans. This information will be analysed to see if there are any links between certain FDG-PET results and whether patients were more or less likely to die from their breast cancer.

What are the possible benefits and risks of participating?
There are no potential risks or benefits to participants.

Where is the study run from?
Brussels University Hospital (Belgium)

When is the study starting and how long is it expected to run for?
July 2015 to January 2020

Who is funding the study?
The investigator is funding the costs of the study.

Who is the main contact?
Dr Vincent Vinh-Hung, vh@onco.be

Contact information

Type(s)
Scientific

Contact name
Dr Vincent Vinh-Hung

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
1.03

Study information

Scientific Title
Prognostic value of pre-treatment 18FDG-PET in operable breast cancer

Acronym
PET2015UZ

Study objectives
18FDG-PET is a significant predictor of outcome in breast cancer.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 21/10/2015, Commissie Medische Ethiek (O.G. 016) Universitair Ziekenhuis Brussel [Brussels University Hospital Medical Ethics Committee] (Reflectiegroep Biomedische Ethiek, Laarbeeklaan 101, 1090 Brussels, Belgium; +32 2 477 55 84; commissie.ethiek@uzbrussel.be), ref: B.U.N. 143201525542

Study design
Single-centre retrospective observational study with longitudinal cohorts 2002-2008 and 2009-2015

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Operable breast cancer.

Interventions
Records of patients with breast cancer who received pre-operative 18FDG-PET scans will be included. The records will be anonymised and the following types of data extracted:
1. Clinical-pathological characteristics, including age at diagnosis, histological tumor type, pathological grade etc
2. FDG-PET characteristics, including PET positivity and standard uptake value (SUV) etc
3. Outcomes, including local and regional recurrence, disease status at last follow-up, cause of death etc
4. Dates, including date of histological diagnosis, date of recurrence etc

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Overall survival up to 13 years after diagnosis assessed using patient medical records
2. Disease-free survival up to 13 years after diagnosis assessed using patient medical records

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
31/01/2020

Eligibility

Key inclusion criteria
1. Patients treated at the UZ Brussel
2. Diagnosed in the period 2002-2015
3. Primary breast cancer

4. Histologically confirmed
5. Operable
6. Pre-treatment FDG-PET or PET/CT

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
1. Previous history of cancer
2. Primary sarcoma of the breast
3. Palliative surgery for symptom control
4. No histopathological confirmation of cancer
5. Noninvasive carcinoma
6. Metastatic disease demonstrated by imaging modes other than FDG-PET

Date of first enrolment
01/01/2002

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Belgium

Study participating centre
Oncologisch Centrum, UZ Brussel
101 Laarbeeklaan
Jette
Belgium
1090

Sponsor information

Organisation

Universitair Ziekenhuis Brussel

ROR
https://ror.org/038f7y939

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated at the analysis of the study will be made available upon request from the main contact, Vincent Vinh-Hung (vh@onco.be or anhxang@gmail.com), who will inform the UZ Brussel Ethics Committee.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		24/04/2022	14/06/2023	Yes	No
Results article		10/03/2021	14/06/2023	Yes	No
Dataset		25/10/2021	14/06/2023	No	No
Protocol file	version v1.03	22/07/2015	12/05/2020	No	No